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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,166	04/26/2001	Edward W. Merrill	37697-0035	7738

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,166

Applicant(s)

MERRILL ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Line 1 of abstract recites "the body" which was not previously defined. It is suggested to replace "the body" with "a body" or "a human body."

- Title of invention is not necessary on abstract page. Removal of title from abstract is suggested.
2. The use of the trademark DECALIN has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. DECALIN is suggested to be capitalized where recited as in claim 128 and in each appearance throughout the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 124-131, 141, 143, and 145-149 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 124 recites the limitation "the body" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 125-131 are dependent claims, thus inherit errors of prior independent claim. Similar errors occur in claims 141, 143, and 145-147. For example, claim 147 recites the limitations "the melting point" and "said polymeric chains" in lines 2 and 3 respectively. There is insufficient antecedent basis for these limitations in the claim. Claims 148 and 149 are dependent upon claim 147; therefore inherit errors of prior claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 139-141 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (U.S. Patent 6,168,626). Hyon discloses a method for making a cross-linked UHMWPE that includes all the limitations recited in the claims. Referring to claim 139, Hyon discloses a method of cross-linking UHMWPE by irradiating, heating and cooling (col.2, lines46-55) as claimed in 139-141. The temperature of providing UHMWPE as disclosed by Hyon, ranges from room temperature (col.3, line44) as claimed in 139, to between room temperature and 90°C (col.3, lines44-46) as claimed in 140, to between 90°C and

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the melting point of UHMWPE (col.3, lines45-46;col.4, lines4-13, 57-60) as claimed in 141. The heat generated is sufficient to at least partially melt the UHMWPE (col.4, lines4-16) as claimed in 139-141. Hyon discloses a cross-linked polyethylene, which is heated to a temperature below the melting point (col.4, lines5-9) as claimed in 147. Hyon discloses a method, which irradiates to cross-link, heats to at least partially melt, and cools said polyethylene (col.2, lines46-55) as claimed in 147. Referring to claim 148, Hyon discloses an irradiation temperature, which would melt the polyethylene (col.3, lines39-46). Referring to claim 149, Hyon discloses an additional heating step, which melts the polyethylene (col.4, lines4-16).

Claim Rejections - 35 USC § 103

Claims 124, 126-127, 129, 132, and 134-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon et al (U.S. Patent 6,168,626 B1) in view of Howard, Jr. et al. (U.S. Patent 5,684,124). Hyon discloses the invention substantially as claimed. Hyon discloses a medical prosthesis (artificial joint and other medical uses, col.7, lines51-59) made of ultra high molecular weight polyethylene (UHMWPE, col.2, lines42-46) as claimed in 124.

Hyon discloses a UHMWPE that has been cross-linked by radiation (col.2, lines 46-55) as claimed in 124 and132. Hyon discloses a UHMWPE, which is subjected to heating by irradiation (col.1, lines40-46; col.2, lines4-15, 58-65) as claimed in 127 and 135.

Hyon discloses a UHMWPE with a molecular weight greater than 1 million (2-8 million, col.3, lines 21-23) as claimed in 129.

Hyon discloses a UHMWPE having most of the limitation in the claims. However, Hyon discloses a UHMWPE, which has only one melting peak (col.3, lines 23-24). Howard teaches in the same field of endeavor, a UHMWPE medical prosthesis (col.1, lines21-29), which has multiple melting peaks (col.3, lines29-36), specifically two melting peaks, as claimed in 126 and 134, in order to improve cross-

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linking. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the medical prosthesis of Hyon and a UHMWPE with multiple melting peaks such as Howard, in order to improve cross-linking and thus, increase the mechanical properties of the polymer.

8. Claim 130 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon et al. (U.S. Patent 6,168,626 B1). Hyon discloses a UHMWPE medical prosthesis with applications such as hip, knee, elbow, finger, and shoulder joints and the like (col.1, lines25-28). Hyon does not disclose an application for an ankle joint. However, it is common knowledge in the prior art that an ankle joint is an articulating joint, which is commonly treated as an equivalent to articulating joints previously listed. Materials used for said joints may also be used for ankle joints as well.

9. Claim 125 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon et al. in view of Howard Jr. et al. as applied to claim 124 and 132 respectively above, and further in view of Bashir et al. (U.S. Patent 5,001,206). Hyon in view of Howard disclose the invention substantially as claimed. However, Hyon and Howard disclose a UHMWPE with only one or two (respectively) melting peaks. Bashir teaches in the analogous art of polymers, a polyethylene polymer (col.2, lines60-61; col.3, lines23-24) having 3 melting peaks (col.6, lines 23-25) as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a UHMWPE of Hyon in view of Howard with an additional melting peak as Bashir discloses in order to optimize mechanical properties of the implant.

10. Claim 128 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon in view of Howard as applied to claim 124 above, and further in view of Dearnaley et al. (U.S. Patent 5,593,719). Hyon in view of Howard disclose the invention substantially as claimed. However, neither disclose use of xylene or DECALIN. Dearnaley teaches in the same field of endeavor a UHMWPE which is subjected to DECALIN or xylene (col.4, lines21-31) at temperatures similar to as claimed for 24 hours before the solvent is removed (col.4, lines32-64; col.8, lines 58-65) for the purpose of selective dissolution of any

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small, low molecular weight particles, without damaging polymer (col.8, lines63-65), thus reducing wear. It would have been obvious to one having ordinary skill in the art at the time the invention was made to immerse the UHMWPE of Hyon in view of Howard into DECALIN or zylene as disclosed by Dearnaley, for an extended period of time and a high temperature in order to dissolve the maximum amount of small particles which cause wear, without damaging or dissolving the polymer as a whole.

11. Claim 131 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyon in view of Howard as applied to claim 124 and 132 respectively above, and further in view of Parikh et al. (U.S. Patent 6,005,053). Hyon in view of Howard disclose the invention substantially as claimed. Hyon discloses the importance of optimizing properties such as tensile modulus and crystallinity (col.3, lines 12-16, 33-39). Howard also discloses importance of tensile modulus and crystallinity, however his values are high. Parikh teaches in the analogous field of polymers a polyethylene polymer (col.1, line45), which has a crystallinity of less than 50 percent (col.2, lines1-4) and a tensile modulus below 940 Mpa (col.42, line15) for the purpose of improved mechanical properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polyethylene polymer with values of crystallinity and tensile modulus as disclosed by Parikh, for a medical prosthesis as disclosed by Hyon in view of Howard.

12. Claims 137 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent 6,174,934) in view of Howard et al. (U.S. Patent 5,684,124). Sun discloses the invention substantially as claimed. Sun discloses a method for making a UHMWPE (col.1, lines16-20) by irradiating to cross-link (col.4, lines39-43), followed by a cooling phase (col.5, line67-col.6, line1) as claimed in 137. During irradiation, UHMWPE is heated to a temperature between room temperature and the melting point of the polymer (col.5, lines55-57) as claimed in 138. Sun does not disclose however, a UHMWPE, which has multiple melting peaks. Howard teaches in the same field of endeavor, a UHMWPE, which has multiple melting peaks (col.2, lines36-37;col.19, lines1-4). It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to use a UHMWPE with multiple melting peaks as disclosed by Howard combined with a method of treating UHMWPE as disclosed by Sun in order to optimize mechanical properties, such as crystallinity.

13. Claim 142 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent 6,174,934) in view of Rose et al. (Radiation Sterilization and the Wear Rate of Polyethylene). Sun discloses the invention substantially as claimed. Sun discloses a method of cross-linking UHMWPE to eliminate free radicals (col.5, lines28-39). Said method is completed by irradiation, and heating at a temperature below the melting point of UHMWPE (col.5, lines55-37), followed by a cooling step (col.5, line67-col.6, line1). Sun however, discloses an irradiation dose of 2.5 Mrads (col.7, lines53-55), lower than the dose claimed. Rose teaches in the same field of endeavor, irradiation of UHMWPE in doses above 5 Mrads (p.394, col.2;p.396;Figure3) improves cross-linking without increasing wear. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a high irradiation dose as disclosed by Rose, to method of treating UHMWPE as disclosed by Sun in order to reduce wear of UHMWPE.

14. Claim 143 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (6,174,934) in view of Rose et al. (Radiation Sterilization and the Wear Rate of Polyethylene) as applied to claim 142 above, and further in view of Hyon et al. (U.S. Patent 6,168,626). Sun in view of Rose disclose the invention substantially as claimed. However they do not disclose irradiation at a temperature above the melting point of UHMWPE. Hyon teaches in the same field of endeavor a method of cross-linking UHMWPE (col.2, lines47-55;col.3, lines 62-65) as claimed, which uses a temperature above the melting point of the polymer (col.4, lines4-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of cross-linking as disclosed by Sun in view of Rose, with temperatures disclosed by Hyon in order to partially melt the polymer.

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15. Claim 144 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dearnaley et al. (U.S. Patent 5,593,719) in view of Howard, Jr. et al. (U.S. Patent 5,684,124). Dearnaley discloses the invention substantially as claimed. Dearnaley discloses a method to make a medical prosthesis made of UHMWPE (col.4, lines12-17;col.1, lines21-22, 29-31) as claimed. Said method reduced particles produced during wear (col.3, lines46-60) by radiation (col.4, lines61-64;col.7, lines58-64). Said method is disclosed to produce a load-bearing surface (col.3, lines48-49) as claimed. Dearnaley however, is silent to mention the number of melting peaks associated with the UHMWPE used. Howard teaches in the same field of endeavor, a method of making a UHMWPE used as a load bearing surface in the body (col.1, lines22-29), which has multiple melting peaks (col.2, lines36-37;col.19, lines1-4) in order to optimize mechanical properties such as crystallinity and tensile modulus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method to reduce particles of wear in a UHMWPE such as disclosed by Dearnaley to make a UHMWPE with multiple melting peaks, as disclosed by Howard in order to further optimize mechanical properties of a UHMWPE prosthesis.

16. Claims 145 and 146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dearnaley et al. (U.S. Patent 5,593,719) in view of Rose et al. (Radiation Sterilization and the Wear Rate of Polyethylene). Dearnaley discloses the invention substantially as claimed. Dearnaley discloses a method of making a medical prosthesis made of UHMWPE (col.4, lines12-17;col.1, lines21-22, 29-31) as claimed. Said method was disclosed to reduce particles produced during wear (col.3, lines46-60) by radiation (col.4, lines61-64;col.7, lines58-64) at a temperature above room temperature (col.4, lines32-39). Said method is disclosed to produce a load-bearing surface (col.3, lines48-49) as claimed. Dearnaley however, is silent to mention an irradiation dose applied to the UHMWPE. Rose teaches in the same field of endeavor, an irradiation dose treatment of above 2 and 4 Mrads (p.394, col.1; p394, col.2) as claimed in 145 and 146 respectively, for the same purpose of reducing wear, thus particle production. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use

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a method of making UHMWPE as disclosed by Dearnaley and choosing an irradiation technique similar to what is disclosed by Rose in order to have reduced particle production and wear.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,824,411 to Shalaby et al. discloses an UHMWPE load bearing medical implant, treated with irradiation at room temperature to optimize tensile modulus and wear factor.

U.S. Patent 5,972,444 to Patel et al. discloses a polyethylene polymer having one or more melting peak and low crystalline values.

U.S. Patent 5,001,008 to Tokita et al. discloses an UHMWPE, which is used for medical materials. The UHMWPE having at least two melting peaks is chemically cross-linked and treated with DECALIN at 135°C.

U.S. Patent 4,902,460 to Yagi et al. discloses an UHMWPE, which is cross-linked, heated, treated with DECALIN, and has at least two melting peaks.

U.S. Patent 5,753,182 to Higgins discloses a method for treating prosthetic bearing made of UHMWPE in efforts to reduce free radicals by irradiation.

U.S. Patent 5,066,755 to Lemstra discloses an UHMWPE, which has been irradiated with a dose of about 1-10 Mrads at a temperature below melting point of polymer. The polymer has two melting peaks.

U.S. Patent 4,586,995 to Randall et al. discloses a treatment method for an ethylene polymer, which includes irradiation, heating, and cooling.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday-Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Clm.

12/28/2001


David H. Willse
Primary Examiner